USER MANUAL

EASYPULSE POC

PORTABLE OXYGEN CONCENTRATOR

Model: PM4150 Series

SAVE THESE INSTRUCTIONS

℞ ONLY Federal (USA) law restricts this device to sale by or on the order of a physician.

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RECEIVING / INSPECTION

Remove the Precision Medical, Inc. *EasyPulse* Portable Oxygen Concentrator (POC) from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

The Precision Medical *EasyPulse POC* (model PM4150) is intended to provide supplemental oxygen to persons requiring oxygen therapy. The Precision Medical POC can be used in a home, institution, vehicle and for transportable use.

READ ALL INSTRUCTIONS BEFORE USING

This manual is provided for your safety and to prevent damage to the POC. If you do not understand this manual, DO NOT USE the POC and contact your Provider.

⚠ DANGER

This product is not intended as a life-sustaining or life-supporting device.

EXPLANATION OF ABBREVIATIONS

mL/min	Milliliters Per Minute
LED	Light Emitting Diode
POC	Portable Oxygen Concentrator

SAFETY INFORMATION - WARNINGS AND CAUTIONS

⚠ DANGER Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

PM4150 WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005, 3rd ed), CAN/CSAC22.2 No. 60601-1 (2008) 62NA

Caution! U.S. Federal Law restricts this device to sale by or on the order of a physician.

This device may contain electrical components that are hazardous to the environment. DO NOT dispose device into standard trash. Contact your local waste Management for disposal of Electronic Equipment.

CE 0473 Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards. **(On CE marked Devices ONLY)**

Authorized by FAA for Use Onboard Aircraft
Docket #: FAA-2012-0928

General Warning Sign

NO SMOKING

Follow Instructions for Use

DO NOT Disassemble

General Mandatory Action Sign

NO Oil or Grease

Excessive Heat Warning

Class II Equipment

Type BF Equipment

General Alarm

Direct Current

Power OFF

IPX1 Drip Proof Equipment

Indicator light Colors and Meaning	
Red	Warning - Immediate response by the OPERATOR is required
Amber	Caution - Prompt response by the OPERATOR is requiired
Green	Ready for use

⚠ DANGER

- **DO NOT** smoke, allow others to smoke or have open flames near the POC when in use.
- **DO NOT** use near any type of flame or flammable/explosive substances.
- **DO NOT** allow POC to exceed “Operating or Storage Temperature Specifications”.
- Excessive heating of the Carry Bag can occur if intake vents are blocked.
- Equipment not suitable for use in the presence of flammable anesthetic.

TO REDUCE THE RISK OF ELECTRICAL SHOCK:

- **DO NOT** use while bathing.
- **DO NOT** reach for the POC that has fallen into water. Unplug immediately.
- **DO NOT** attempt to repair POC. Any attempt could result in electrical shock.

⚠WARNING

- Use the POC for its “Intended Use” as described in this manual.
- This POC contains magnetic, ferrous material that may affect the results of an MRI.
- In the event of an equipment alarm or if you are experiencing any signs of discomfort, connect to another source of oxygen and contact your Provider and / or Health Care Professional immediately.
- In certain circumstances oxygen therapy can be hazardous; any user should seek medical advice prior to using this POC.
- Where the prescribing Health care professional has determined that an interruption in the supply of oxygen, for any reason, may have serious consequences to the user, an alternative source of oxygen should be available for immediate use.
- Place the POC on a secure flat surface when not transporting to avoid accidental damage to the POC.
- **ALWAYS** keep at least 6 in. (15.24 cm) away from walls, furniture, and especially curtains that could prevent adequate airflow to the POC.
- **DO NOT** place the POC in a small closed space such as a closet.
- **DO NOT** use extension cords or electrical adapters.
- The POC is designed to operate with a single lumen, adult cannula with a maximum length of 7 ft (2.1 m).
- ***The Setting Knob does not rotate 360°****. Rotating the knob less than the “OFF* (⏻) *position” or over “setting 5” will damage the Concentrator.*
- DO NOT use Components / Accessories not approved by Precision Medical, see “ACCESSORIES / REPLACEMENT PARTS”.
- The POC delivers oxygen in a concentrated form when a breath is taken. An oxygen enrichment of the surrounding area is unlikely.

TO REDUCE RISK OF BURNS, ELECTROCUTION, FIRE, OR INJURY TO PERSONS:

- Keep away from heat or open flame.
- **DO NOT** use an AC or DC Power Adapter with a damaged power cord or plug.
- **DO NOT** use if POC has been dropped or damaged.
- **DO NOT** use oil or grease on the POC.
- **DO NOT** cover the air vents, the POC requires proper ventilation.
- **DO NOT** remove the cover on the POC. Servicing must be performed by a trained professional.

⚠CAUTION

- The POC is designed to be used indoors or outdoors, in the outdoors environment the POC should be used in a “dry location” with Battery only.
- POC is designed to be used in dry conditions, the POC is not to be submerged or operated under water.

CAUTION

DO NOT place any liquids on or near the POC. If any liquid gets on the POC, immediately turn "OFF" the power switch and unplug from the electrical outlet.

SPECIFICATIONS

Dimensions:	Height:	10.1 in	(25.7 cm)
	Width:	6.5 in	(16.5 cm)
	Depth:	4.5 in	(11.4 cm)
Weight:		6.8 lbs	(3.08 kg)
Shipping Weight:		13.1 lbs	(5.94 kg)
Altitude:		Sea level to 9000 ft (2743 m)	
Operating Temperature:		41˚F to 104˚F (5˚C to 40˚C)	
Storage / Transport Temperature:		-4˚F to 140˚F (-20˚C to 60˚C)	
Operating / Storage / Transport			
Relative Humidity:		Up to 95% Non-Condensing	
Oxygen Concentration:		87% to 95%	
Start Up Time		87% O_2 Concentration ≤ 10 min	
Oxygen Minute Volume*:		***Setting 1:***	240 +/-15% mL/min
		Setting 2:	380 +/-15% mL/min
		Setting 3:	520 +/-15% mL/min
		Setting 4:	660 +/-15% mL/min
		Setting 5:	780 +/-15% mL/min
Mode of Delivery:		Pulsed Dose only	
Trigger Sensitivity:		0.50 cmH_2O maximum	
Trigger Delay:		0.11 seconds typical	
Power:	*AC Power Adapter:*	100-240 VAC	(1.0 A @ 120 VAC)
	DC Power Adapter:	11-16 VDC	(5.0 A @ 12 VDC)
Battery Duration:		***Setting 1:***	4.5 hrs
(Approximate)		***Setting 2:***	3.2 hrs
		Setting 3:	2.5 hrs
		Setting 4:	1.8 hrs
		Setting 5:	1.5 hrs
Sound (@ Setting 2)**:**		44 dBA	

Cannula: Maximum 7 ft (2.1 m) long standard adult single lumen nasal cannula.

Equipment Classification:

Class II	- with respect to protection from electrical shock
Type BF	- degree of protection against electrical shock
IPX1	- degree of protection against ingress of liquids
Mode of Operation	- Continuous

Volatile Organic Compound (VOC) and Particulate Requirements:

The oxygen delivered from the EasyPulse POC meets the following requirements for particulate levels, VOC levels, carbon monoxide levels, carbon dioxide levels and ozone levels.

EPA $PM_{2.5}$	Particulate Matter
ASTM D5466	Ozone Levels
21 CFR 801.415	Carbon Monoxide Levels
EPA NAAQS - Carbon Monoxide	Carbon Dioxide Levels

OSHA Permissible Exposure Limits

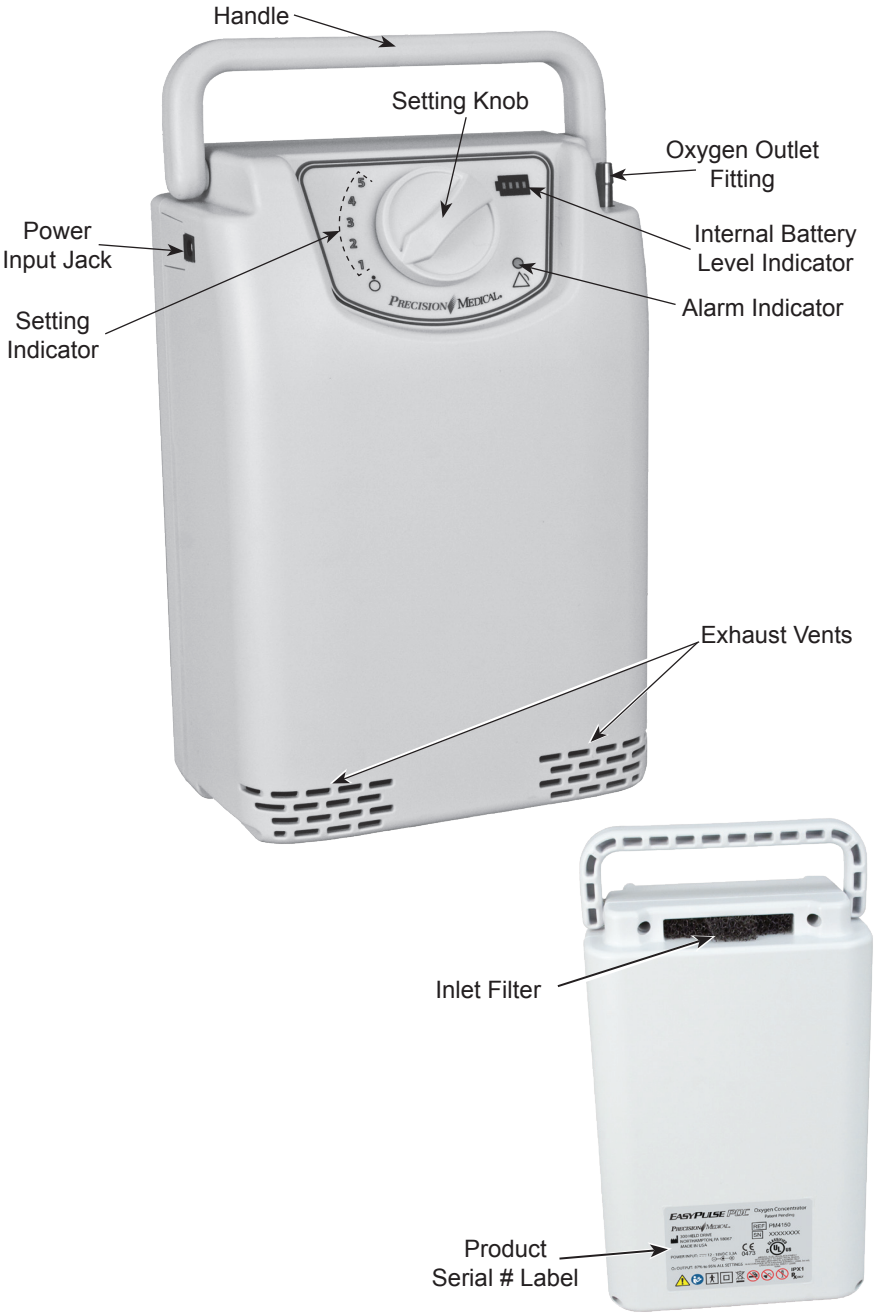
Standard Test Method for Determination of Volatile Organic Chemicals in Atmospheres (Canister Sampling Methodology)

* At Sea level

Specifications are subject to change without prior notice.

COMPONENT DESCRIPTION

⚠CAUTION
Missing or illegible labels must be replaced, contact Precision Medical, Inc.



OPERATING INSTRUCTIONS

⚠WARNING

- Read this User Manual before operating the POC.
- The POC shall be used by an adult or supervised by an adult when being used by a child.
- Additional monitoring or attention may be required for patients using this POC who are unable to hear or see alarms or communicate discomfort.
- ***The Setting Knob does not rotate 360°****. Rotating the knob less than the "OFF (⏻) position" or over "setting 5" will damage the Concentrator.*

⚠CAUTION

- **ALWAYS** confirm prescribed dose before administering to patient and monitor on a frequent basis.
- For Proper Oxygen Flow, be sure that cannula is not kinked or obstructed before or during use.
- **DO NOT** use humidifier bottles with the POC.
- **DO NOT** use pediatric, low flow nasal cannulas or oxygen masks with the POC.

CAUTION

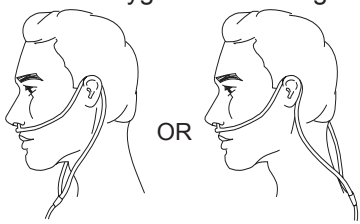
- Inspect the POC for visual damage before use, DO NOT USE if damaged.
- To prevent damage to the POC, **DO NOT** operate the POC without the inlet filter or while the inlet filter is wet.

Using the EasyPulse POC

1. Verify battery status (level) prior to each use, charge as necessary.
2. Connect the end of a standard adult single lumen oxygen nasal cannula with a maximum length of 7 feet (2.1 m) to the POC's oxygen outlet fitting.

To ensure proper device operation, use only an adult single lumen cannula maximum 7 ft (2.1 m).

3. Place the cannula over your ears and position the prongs in your nose as instructed by your Equipment Provider or cannula manufacturer.



4. Prior to operation, ensure the inlet and exhaust vents on the POC are clear. Any blockage of the vents can inhibit performance.
5. Choose one of the 3 power options: AC Power Adapter, DC Power Adapter or Internal Battery (Refer to the "POWER SUPPLY" section of the user manual for details on these 3 options).
6. Turn "ON" the POC by rotating the setting knob ***clockwise*** until the knob points to your prescribed flow setting number and the number is illuminated green.
7. Breathe normally through your nose. A measured pulse of oxygen will be delivered each time the POC senses an inhalation. To show the POC is triggering properly the illuminated setting number will turn off briefly each time it senses an inhalation.
8. To turn "OFF" the POC, rotate the setting knob ***counterclockwise*** to the "OFF" (⏻) position.

Operating Position

The POC can be operated in an upright position with or without the carry bag as shown below.

The POC can be operated lying on its back ONLY while in the carry bag as shown below.

Using the Carry Bag

The carry bag is intended to make the POC easier to transport, prevent movement due to vibration and protect the device from minor mishaps.

CAUTION
The carry bag is not intended to make the POC waterproof, or to protect the device from major falls or accidents/abuse.

When inserting the POC into the carry bag make sure of the following:

- Before placing POC inside bag make sure bag is clean and empty.
- Make sure the control knob and control panel are aligned with the clear window on the bag.
- Make sure bottom exhaust vents are aligned with the mesh opening along the bottom of the bag.

Control panel and clear window properly aligned

Exhaust vents and mesh area properly aligned

Proper carrying position

⚠WARNING	
	• The mesh on the carry bag must be aligned with the exhaust vents on the POC to keep the POC cool and operating properly. • Be sure the exhaust vents are facing away from body while being carried. • If the outside of the bag feels hot or causes any discomfort, set the POC down and check to be sure all vents are unobstructed. • **DO NOT** cover Air Vents, the POC requires proper ventilation. • **DO NOT** allow the POC to come in direct contact with skin while in the carry bag.

The carry handle can be placed in either of the positions below with the flap secured.

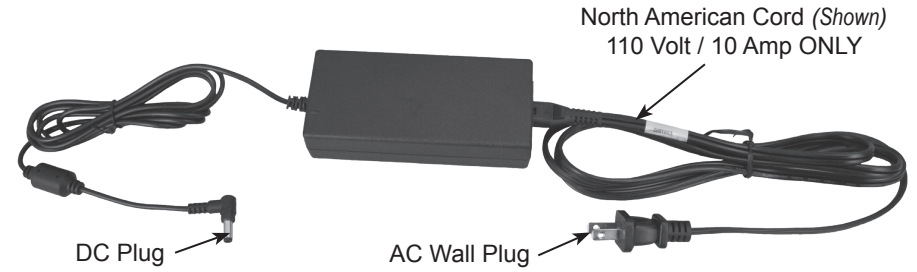
POWER SUPPLY

To prevent damage to the device, use only Precision Medical approved external power sources.

AC Power Adapter:

The AC power adapter connects the POC to a 100-240 VAC, 50/60 Hz wall outlet. The power adapter converts AC voltage to DC voltage in order to power the POC. The AC adapter will power the POC and simultaneously charge the internal battery.

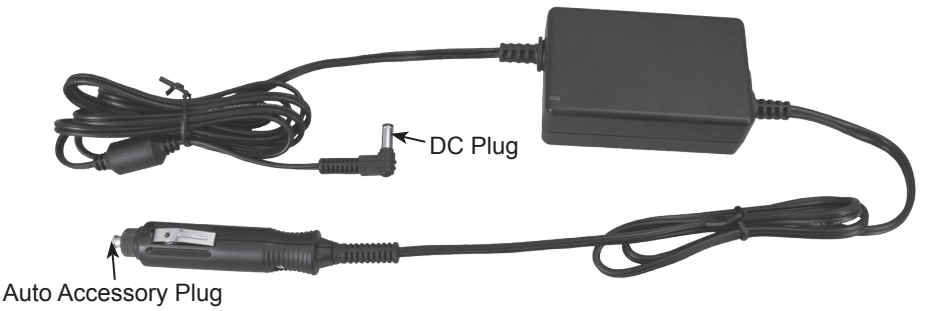
Connection: To connect the AC Power Adapter to the POC, insert the DC plug connector into the power input jack on the POC and insert the AC wall plug into a wall socket.



DC Power Adapter:

The DC power adapter connects the POC to an automobile's 12 VDC outlet. The DC adapter will power the POC and simultaneously charge the internal battery.

Connection: To connect the AC Power Adapter to the POC, insert the DC plug connector into the power input jack on the POC and insert the other end into your automobile's 12 V accessory jack.



Internal Battery Pack:

The POC contains an internal rechargeable lithium ion battery pack. When fully charged, the battery will power the POC for up to 4.5 hours dependent upon setting. The Battery Level Indicator in the upper right corner of the control panel continuously displays the charge level of the internal battery while the POC is on. When the battery charge level drops to 15%, the last LED will turn solid red and a brief audible beep will be emitted once every minute. When the battery charge level drops to 5% the last LED starts to flash red and a brief audible beep is emitted once every 20 seconds to signal that the battery is almost depleted and you will need to connect the POC to another power source.

ENSURE BATTERY IS FULLY CHARGED PRIOR TO FIRST USE.

Charging: The internal battery can be charged by connecting either the AC Power Adapter or DC Power Adapter to the POC. The internal battery will begin charging as soon as power is connected. You will also be able to run the POC while the internal battery charges.

Lithium Ion Battery Guidelines

Proper Use:	***Storage:***
In order to prolong life of the battery, it is best to charge the battery frequently rather than waiting until the battery is fully discharged.	*When storing for long periods of time without use (> 1 month) be sure to charge the battery to around 50% charge level to prolong life of battery.*

ACCESSORIES / REPLACEMENT PARTS

Only the items listed below are to be used with the POC.

Description	***Part #***
Inlet Filter	505847
AC Power Supply	506629
DC Power Supply	506750
Carry Bag	506707
Cannula	504833

Other Power Cord / Plug combination for the AC Power Adapter available thru Precision Medical, Inc. ONLY.

ALARM / INDICATORS / TROUBLESHOOTING

Green	Ready for use
Amber	Caution - Prompt response by the OPERATOR is required
Red	Warning - Immediate response by the OPERATOR is required

The Audible Alarm and LED Indicators are listed in the chart.

Visual Indicator/ Problem	Audible Alarm	Probable Cause	Remedy
The last LED on the internal Battery Level Indicator turns red	Repetitive beep	Internal battery has dropped below 15% charge remaining	Connect the POC to the AC Power Adapter, DC Power Adapter, or external battery pack
The last LED on the internal Battery Level Indicator flashes red	Repetitive beep	Internal battery has dropped below 5% charge remaining	1. Connect the POC to the AC Power Adapter, DC Power Adapter, or external battery pack 2. Change to alternate oxygen source if power source is not available
Amber alarm indicator is illuminated and setting number is not flashing during inhalation to signal a detected breath	Repetitive beep	No breath detected for 1 minute	1. Verify the cannula is not kinked 2. Verify the cannula is properly connected to oxygen outlet 3. Verify the cannula is properly positioned in the nose
Red alarm indicator is illuminated and setting number is not flashing during inhalation to signal a detected breath	Repetitive beep	No breath detected for 2 minutes	1. Verify the cannula is not kinked 2. Verify the cannula is properly connected to oxygen outlet 3. Verify the cannula is properly positioned in the nose 4. If alarm persists change to alternate oxygen source and contact your Equipment Provider
Amber alarm indicator is illuminated	Repetitive beep	Breath rate exceeding 35 breaths / minute	Reduce level of activity to allow breath rate to slow
Red alarm indicator is illuminated	Repetitive beep	Breath rate exceeding 35 breaths / minute for longer than 1 minute	1. Reduce level of activity to allow breath rate to slow 2. If alarm persists, change to alternate oxygen source and contact your Equipment Provider
Red alarm indicator is illuminated, unit is not running and setting numbers 1 & 2 are flashing	Repetitive beep	Abnormal compressor operation detected	1. Turn the POC to the “OFF” position 2. Turn the POC back “ON” to prescribed setting 3. If alarm persists, change to alternate oxygen source and contact your Equipment Provider

Visual Indicator/ Problem	Audible Alarm	Probable Cause	Remedy
Red alarm indicator is illuminated, unit is not running and setting numbers 1 & 3 are flashing	Repetitive beep	Internal battery is outside its operating temperature range	1. Turn off the POC and disconnect any power supplies 2. Check that the inlet filter is clean 3. Ensure inlet and exhaust vents are not blocked in any way 4. Verify you are operating the POC within the specified operating temperature range. 5. It may be necessary to allow the POC to warm up or cool before turning back “ON”
Red alarm indicator is illuminated, unit is not running and setting numbers 1 & 4 are flashing	Repetitive beep	Motor is above its maximum operating temperature	1. Turn off the POC 2. Check that the inlet filter is clean 3. Ensure inlet and exhaust vents are not blocked in any way 4. Verify you are operating the POC within the specified operating temperature range 5. It may be necessary to allow the POC to cool before turning back “ON”
Red alarm indicator is illuminated, unit is not running and setting numbers 1 & 5 are flashing	Repetitive beep	Pressure outside of normal operation	1. Turn the POC to the “OFF” position 2. Turn the POC back “ON” to prescribed setting 3. If alarm persists, change to alternate oxygen source and contact your Equipment Provider
Red alarm indicator is illuminated, unit is not running and setting numbers 2 & 3 are flashing	Repetitive beep	Fan malfunction	1. Turn the POC to the “OFF” position 2. Turn the POC back “ON” to prescribed setting 3. If alarm persists, change to alternate oxygen source and contact your Equipment Provider
Red alarm indicator is illuminated, unit is not running and setting numbers 2 & 4 are flashing	Repetitive beep	Failed electrical connection	1. Turn the POC to the “OFF” position 2. Turn the POC back “ON” to prescribed setting 3. If alarm persists, change to alternate oxygen source and contact your Equipment Provider
Amber alarm indicator is flashing and unit is running	NA	Service Needed	1. Continue to use POC 2. Contact Equipment Provider
Red alarm indicator is flashing and unit is running	NA	Service Needed	1. Switch to another source of oxygen 2. Contact Equipment Provider

MAINTENANCE / CLEANING

⚠WARNING

- Prior to cleaning, ensure the POC is turned off and unplug any external power sources.
- **DO NOT** disassemble or attempt to repair. There are no user serviceable parts inside. Contact your Equipment Provider for service.
- **DO NOT** spray or apply any cleaners directly onto the case.
- **DO NOT** allow any liquids to drip inside any case openings.
- **DO NOT** use harsh and/or flammable chemicals to clean the device.

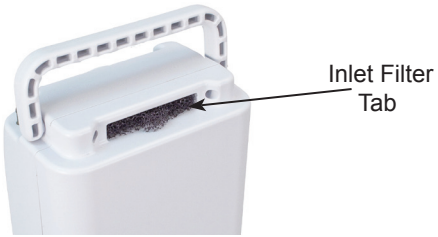
Perform cleaning as required.

Cabinet:

1. The patient should connect to an alternate Oxygen source.
2. Turn the POC to the “OFF” (⏻) position.
3. Unplug the external power source before cleaning.
4. Clean exterior surfaces of the POC with a cloth dampened with disinfectant solution. *Example: Sporicidin® Brand Disinfectant Solution.*
5. Allow POC to air dry.
6. DO NOT place inside carry bag or run the POC until it is thoroughly dry.
7. When not in use, store the POC in a clean area free from grease, oil and other sources of contamination.

Inlet Filter:

1. Remove the inlet filter by pulling on the protruding tab.
2. Wash filter with mild detergent. Rinse thoroughly with water and allow to dry completely.
3. Once filter is dry, push the filter back into the case so only the small tab is protruding.



RETURNS

Returned products require a Returned Goods Authorization (RGA) number, contact Precision Medical, Inc. All returns must be packaged in sealed containers to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Refer to Precision Medical, Inc. Return Policy available on the Internet, www.precisionmedical.com.

Manuals available on our Website; www.precisionmedical.com

DISPOSAL INSTRUCTIONS

This device may contain electrical components that are hazardous to the environment. DO NOT dispose device into standard trash. Contact your local waste Management for disposal of Electronic Equipment.

LIMITED WARRANTY
AND
LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Portable Oxygen Concentrator POC, (the Product), will be free of defects in workmanship and/or material for the following period:

Portable Oxygen Concentrator	*three (3) years from date of shipment*
Battery	*180 days from date of shipment*

Precision Medical, Inc. is NOT responsible for normal wear and tear, or any neglect or abuse of the product.

Precision Medical, Inc. is NOT responsible for the shipping cost of the repair.

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representatives of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.

DECLARATION OF CONFORMITY

Precision Medical, Inc.
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Northampton PA 18067, USA

EC REP

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CE 0473

REF PM4150

Classification: IIa

Classification criteria: Clause 3.2 Rule 11 of Annex IX of MDD

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II, 3 of the Directive 93/42/EEC and Directive 2007/47/EC on medical devices.

We certify that the production quality system conforms to the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed above.

Applied Standards: *EN 1041, EN ISO 14971, EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-8, EN 62366, EN ISO 3744, EN ISO 8359, EN ISO 15001, ISO 13485, ISO 15223-1, 2006/66/EC*

Notified Body: Intertek AMTAC Certification Services Limited CE 0473
Address: Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK
Certification Registration No's: 1126 A CE
Date of Expiry: 26 July 2017
Devices already manufactured: S/N traceability Device History Records
Validity of DOC: 31 August 2012 to Date of Expiry
Manufacture Representative: Quality Manager
Position: Quality Systems/ISO Representative
Date of Issue: 31 August 2012

Tell us how we are doing!
Visit us at www.precisionmedical.com